



Roex, Inc.

February 10, 1998

RECEIVED  
2/17/98

Office of Special Nutritionals  
Center for Food Safety and Applied Nutrition  
Food & Drug Administration  
200 "C" St., S.W.  
Washington, DC 20204

RE: Notification of Nutritional Support Statements

To Whom it May Concern:

Please be advised that:

Roex, Inc.  
2081 Business Center Dr., Ste. 185  
Irvine, California 92612

is engaged in distributing a dietary supplement which contains the following statements:

"Assists in promoting a healthy prostate."

"Roex® Advanced Men's Formula has been designed to provide complete nutritional support for a healthy prostate with herbs complemented by nutrients known to be essential for its proper function. This advanced formula contains standardized herbal extracts of Saw Palmetto, Pygeum, and Cranberry, and a phytosterol complex providing Stinging Nettle, Soybean Phytosterol, and Pumpkin Seed. Additional nutritional support is provided by vitamins B<sub>6</sub>, D, E, amino acids glycine, lysine and glutamic acid and the essential mineral Zinc. Numerous clinical studies have shown the effectiveness of these nutrients in promoting healthy prostate."

Which appears on the product named:

Roex® Advanced Men's Formula

Containing:

Vitamins B<sub>6</sub>, D, E, Zinc, L-glycine, L-lysine, L-glutamic acid, Saw Palmetto berry & extract, Pygeum bark extract, Stinging Nettle root, Cranberry fruit extract, Pumpkin seed, Echinacea herb and Soybean Phytosterol.

I, Kathryn K. McDaniel, certify that the information contained in this notice is complete and accurate and that substantiation exists to verify the accuracy and veracity of the referenced statements.

Signed: Kathryn K. McDaniel  
Kathryn K. McDaniel  
Product Development &  
Regulatory Compliance Manager  
Roex, Inc.

Dated: February 10, 1998  
February 10, 1998

2081 BUSINESS CENTER DRIVE, SUITE 185, IRVINE, CALIFORNIA 92612

KKM/kk (714) 476-8675 • FOR ORDERS: (800) 645-0010 • DIRECT SALES: (888) 727-2707 • SPANISH ONLY: (800) 541-4588

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FAX: (714) 476-8682 • INTERNET: <http://www.roex.com>

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